

DARKIN et al.
Appl. No. 10/579,221
March 24, 2010

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to Fig. 14.

Attachment: Replacement Fig. 14

REMARKS/ARGUMENTS

Claims 1-50 are pending. By this Amendment, the specification, Fig. 14 and claims 29 and 30 are amended, and new claims 32-50 are added. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

The Office Action indicates that claims 27 and 28 are directed to an invention that is independent or distinct from the invention originally claimed, and that the originally presented invention has been constructively elected. The Office Action withdraws claims 27 and 28 from consideration.

The Office Action objects to the drawings under 37 C.F.R. 1.83(a) as failing to show the nozzle elements, positioning structure and alarm. Attached hereto is a revised Fig. 14 showing the nozzle elements. The patient interface frame 210 is illustrated in Figs. 11a-14, with Fig. 14 revised to illustrate the nozzles 211. A corresponding amendment is made to the specification referring to the nozzles. These revisions do not constitute new matter as one of ordinary skill in the art would understand the nozzles so positioned. This type of nozzle configuration is well known, as shown in US Pat. 7,318,437, which has a common inventor with the present application. See for example Figs. 61, 76B, etc. of the '437 patent, which show a substantially similar frame as shown in Fig. 11a-14 of the present application, both of which frames are constructed to receive a pair of nozzles. Approval is requested.

As previously asserted, the positioning structure is shown and described in relation to the embodiment of Figure 20. For example, the vent assembly 300 includes an alignment arrow 312 molded on a shaft 302, whereas each vent 308, 310 has an adjacent indicator 309, 311, molded

onto the sleeve 304. The indicators may present a characteristic feel depending on the vent position so that they can be recognized in the dark. Additionally or alternatively, the vent assembly may exhibit a characteristic “click” as its vents are changed as shown in Figure 20. See paragraphs [0091] and [0061] of the original application. Thus, Applicants respectfully submit that the positioning structure is adequately shown in the original application figures.

The alarm is also shown and described in relation to the embodiment of Figure 20. For example, the flow generator may prompt the selection of the optimum vent for a given control algorithm or air circuit configuration. Having detected the selection of a vent, the flow generator may present a message to the user. The message may be by way of an auditory or visual alarm. See paragraphs [0094] of the original application. Thus, Applicants respectfully submit that the alarm is adequately shown in the original application figures.

Therefore, withdrawal of the objection to the drawings is respectfully requested.

The Office Action rejects claims 4, 15, 16, 25 and 26 under 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed.

The nozzle elements of claim 4 are shown in replacement Fig. 14 and described in [0069], as described above.

The connection between the alarm and the positioning structure and the connection between the alarm and a higher noise level are set forth in the specification. In particular, the original specification provides support for an alarm that is sounded if the vent assembly is not in the first or second position. For example, if the vent is not in the first or second position, an alarm can be created. See paragraph [0061] of the original specification. Also, paragraph [0092]

of the specification indicates that when the appropriate vent 352 or 354 is aligned over an orifice, a corresponding resistor 353 or 355 electrically connects a connector 356 which is in electrically communication with the flow generator controller 358. Moreover, assuming that the appropriate vent 352 or 354 is not aligned over the orifice, an alarm may be sounded. See also paragraph [0090] which specifies that the message to the user may be by way of an auditory or visual alarm. In another example, the alarm may be generated if the noise level produced by the selected vent is a predetermined threshold (see claims 16 and 26). The noise level of the alarm can be detected by use of standard sound transducers, e.g., a microphone.

Reconsideration and withdrawal of the rejection are respectfully requested.

The Office Action rejects claims 1 and 4 under 35 U.S.C. § 102(b) as being anticipated by Humphries (1,125,542). This rejection is respectfully traversed.

The Office Action asserts that Humphries discloses what is inherently a nasal mask assembly in that it covers the nostrils of a patient, a frame (a, b), a cushion in the form of two nozzle elements (c) to be inserted into the nostrils of a user, and a vent assembly including a first vent (s) and a second vent (u) wherein a clip (o) slides around the frame to select between the two vents, referring to page 2, lines 4-15.

However, Humphries does not disclose a vent assembly including a first vent, a second vent, and a selector to switch the flow of exhaled gas from the patient between the first and second vents, as recited in claim 1. Humphries instead discloses a combined air admission and expiration valve having a cylinder *n* opening upward from tube *a*, and covered by a cap *o* fitting over it. The top of the cylinder *n* is formed as a valve seat with a diaphragm valve *p* adapted to

close the entry into the top of the cylinder, and which is kept normally on its seat by means of a light spring *r*. Apertures *s* are made in the wall of the cap above the level of the valve so that as the patient exhales through the nostrils, the exhalations lift up valve *p* and the exhalations escape through the apertures *s*. When exhalation ceases, the valve reseats itself and prevents entry of air through it. See page 1, col. 2, lines 93-111.

In contrast, ports *t* and *u* formed in the cylinder and in the cap beneath the valve *p* allow entry of air into the tube by rotation of the cap making the ports coincident with one another. See page 2, col. 1, lines 4-15. Thus, Humphries does not disclose a vent assembly including a first vent, a second vent, and a selector to switch the flow of exhaled gas from the patient between the first and second vents, as recited in claim 1 of the application, but instead discloses the apertures *s* allowing patient exhalations to escape, and the ports *t* and *u* allowing entry of air into the tube when the cap is rotated to line up the ports. Humphries does not switch the flow of exhaled gas from the patient between first and second vents.

Moreover, the Office Action does not indicate what structure in Humphries it considers to be equivalent to the claimed selector to switch the flow of exhaled gas from the patient between the first and second vents as recited in claim 1 of the application. Humphries does not include such a selector to switch the flow of exhaled gas from the patient between first and second vents. For the above reasons, claim 1 of the application is not anticipated by Humphries.

Regarding claim 4, the Office Action asserts that Humphries discloses a clip (*o*) that slides around the frame to select between the two vents. However, Humphries discloses a cap *o* placed over cylinder *n*, with ports *t* and *u* formed in cylinder *n* and in the cap *o* beneath the valve

p, that allows entry of air into the tube by rotation of the cap when the ports are made coincident with one another. Humphries does not disclose a selector that includes a clip that is slidable with respect to the frame to select between the first and second vents. Rotation of the cap allows lining up of ports *t* and *u*, but does not disclose a slidable clip that selects between the first and second vents, to switch the flow of exhaled gas from the patient between the first and second vents, as recited in claim 4. For the above reasons, claim 4 of the application is not anticipated by Humphries. Withdrawal of the rejection is requested.

The Office Action rejects claims 1-3, 5-26 and 29-31 under 35 U.S.C. § 103(a) over Bauman (4,821,713) in view of Gradon (6,662,803). This rejection is respectfully traversed.

Regarding claims 1 and 17, the Office Action asserts that Bauman discloses a mask assembly comprising a vent assembly including a first vent 127, a second vent 126 and a selector switch 121 to switch the flow of exhaled gas from the patient between the first and second vents, referring to col. 5, lines 3-20.

However, Bauman discloses that the rotor or rotatable cap 121 is part of air bleed means 120, for controlling the amount of air passing to the patient in the mask. See col. 4, line 53 through col. 5, line 20. The rotatable cap 121 is not a switch to switch the flow of exhaled gas from the patient between the first and second vents, as recited in independent claims 1 and 17 of the application, but instead is used to control the amount of air delivered to the patient.

Further, the resuscitator of Bauman utilizes re-entrant duct 70 defining air discharge port 71 in communication with air outlet 19 for discharging air exhaled by the patient. See col. 3, line 66 through col. 4, line 8. The air discharge port 71 does not disclose a switch to switch the flow

of exhaled gas from the patient between the first and second vents, as recited in independent claims 1 and 17. Instead, the one and only air discharge port 71 is fixed. Further, flap valves 31 and 32 isolate air bleed means 120 from the patient during exhalation, specifically "...upon exhalation by the patient, flap valve 32 being closed against seat 32b. Exhaled lung air then escapes via duct 70." See col. 3, line 66- col. 4, line 3 and col. 3, lines 13-24. As a result, no exhaled gases are intended to pass through air bleed means 120. Gradon does not solve the above deficiencies of Bauman regarding claims 1 and 17.

For the above reasons, claims 1 and 17 and all claims dependent therefrom would not have been obvious over Bauman in view of Gradon.

In addition, neither Bauman nor Gradon disclose a vent assembly provided to the frame having a first vent portion with a first flow capacity and a second vent portion with a second flow capacity, the first vent portion and the second vent portion for venting exhaled gases from the patient, and a slidable selector to switch between the first and second vent portions, as recited in independent claim 29. The rotatable cap 121 is part of air bleed means 120, for controlling the amount of air passing to the patient in the mask, and is not a first vent portion and a second vent portion for venting exhaled gases from the patient. Gradon does not solve these deficiencies. For these reasons, claim 29 and all claims dependent therefrom would not have been obvious over Bauman in view of Gradon. Withdrawal of the rejection is requested.

New claims 32-50 depend from one of independent claims 1, 17 or 29 are believed to be allowable for at least the reasons set forth above.

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The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4398-537.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below

Respectfully submitted,

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